EXHIBIT 1

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

) MDL No. 1456
IN RE PHARMACEUTICAL INDUSTRY) Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE)
LITIGATION) (Original Central District of California
	_) No. 03-CV-2238)
)
THIS DOCUMENT RELATES TO:) Judge Patti B. Saris
State of California, ex rel. Ven-A-Care v.)
Abbott Laboratories, Inc., et al.	
CASE #: 1:03-cv-11226-PBS	
	_)

<u>DEFENDANTS' RESPONSE TO PLAINTIFFS' SUPPLEMENTAL SUBMISSION</u> <u>IN RESPONSE TO THE COURT'S REQUEST FOR CLAIMS EXAMPLES</u>

Plaintiffs' Supplemental Submission In Response To The Court's Request For Claims Examples (the "Supplemental Submission") is a desperate attempt to avoid dismissal of their First Amended Complaint-In-Intervention. Specifically, Plaintiffs' Supplemental Submission (which purports to provide examples of claims for each drug that allegedly was fraudulently billed to California's Medicaid program, Medi-Cal) fails to remedy any of the many defects in the First Amended Complaint-In-Intervention ("FAC") for two separate reasons:

- It is incomplete and misleading because it includes only select information from providers' claims for a subset of the NDCs named in the FAC; and
- It fails to demonstrate the existence of any false claims.

The Court should not be distracted by Plaintiffs' eleventh hour attempt to remedy their defective pleading. Defendants' motion to dismiss should be granted.

BACKGROUND

As set out in Defendants' motion to dismiss, Plaintiffs' FAC is procedurally and substantively deficient, requiring dismissal of all counts under either, or both, of Federal Rules of Civil Procedure 9(b) and 12(b)(6). In particular, among other reasons, the FAC fails to satisfy

Rules 9(b) and 12(b)(6) because it does not plead the particulars of any of the allegedly "false claims" that formed the basis of each count in the FAC. After this deficiency was highlighted at the May 22, 2006 oral argument on Defendants' motion to dismiss – and, indeed, more than two months after that hearing -- Plaintiffs moved for leave to file their Supplemental Submission.

Shortly thereafter, on August 4, 2006, Defendants filed an opposition to Plaintiffs' motion for leave, arguing, among other things, that Plaintiffs' Supplemental Submission was untimely. On September 11, 2006, this Court granted Plaintiffs' motion for leave and on September 12, 2006, Plaintiffs re-filed their Supplemental Submission. Defendants submit this response to demonstrate that the Supplemental Submission is incomplete and misleading, and in any event, fails to remedy the many defects in Plaintiffs' FAC.

ARGUMENT

The sine qua non of a False Claims Act violation is, of course, the existence of a *false claim*. While Plaintiffs' FAC has many defects, its failure to allege the existence of a false claim, with the particularity required by Rule 9(b), is one of the more glaring omissions.

Plaintiffs' Supplemental Submission purports to remedy that defect by providing some information relating to the alleged false claims that form the basis of the FAC. The alleged claims information contained in Exhibit B of Plaintiffs' Supplemental Submission, however does not save the day for Plaintiffs for either of two reasons.

First, Plaintiffs' Supplemental Submission is incomplete and misleading. Plaintiffs have merely hand-picked certain information from providers' electronic claims. Indeed, for each example, Plaintiffs include only 4 of the approximately 30 fields of information in the electronic

¹ This case was originally filed in 1998 and Plaintiffs have had ample time since then to amend their complaint to attach provider claims. Plaintiffs, however, chose not to do so. Defendants argued that it was completely inappropriate for Plaintiffs to present this extrinsic evidence, which is neither part of the FAC or public record, to the Court, in this fashion, at this late date.

claim that providers typically submit to Medi-Cal. (*Compare* Pls.' Ex. B *with* Pls.' Ex. D at 2-11.) The only information submitted by providers contained in Exhibit B is the NDC for the drug billed, the provider's identity, the number of units billed, and the provider's billed amount. The remaining columns in Exhibit B, including the amount paid by Medi-Cal, were provided by Plaintiffs or Medi-Cal. They are not part of the providers' claim. In fact, contrary to Plaintiffs' suggestion (*see* Supplemental Submission at 2, n.1), many of the missing claim fields have information that could be relevant to this case and is not HIPAA protected, such as the Medi-Cal recipient's "Share of Cost," which represents the co-payment collected by the provider. (*See* Pls.' Ex. D at 6.)

Additionally, Plaintiffs did not provide an example claim for each NDC named in the FAC. Rather, Plaintiffs provided an example for each Defendant's drugs, which may have several different NDCs. There is no legitimate reason why Plaintiffs could not provide an example of a complete claim for each of the NDCs named in the FAC, and their failure to do so (as well as their failure to provide any particulars regarding Defendants' alleged fraud scheme for each of the counts in the FAC) warrants dismissal of the FAC pursuant to Rule 9(b).

Second, Plaintiffs' Supplemental Submission fails to remedy any defects in the FAC because it fails to show the existence of a *false* claim. To the contrary, the limited claims information that Plaintiffs did submit confirms that Plaintiffs' FAC fails to allege the existence of a false claim – a defect that is fatal to Plaintiffs' False Claims Act case. While Plaintiffs' Supplemental Submission attempts to conflate the claims submission process with Medi-Cal's choice about the amount of reimbursement to pay providers, the FAC is clear that the alleged "false" claims that form the basis of Plaintiffs' cause of action are the claims submitted by providers to Medi-Cal for reimbursement:

The claims which are the subject of this action were submitted to Medi-Cal for reimbursement for prescription drugs provided to Medi-Cal beneficiaries. Claims for each prescription are submitted on hard copy claim forms or through an electronic claim filing procedure using drug identification numbers known as National Drug Code ("NDC") numbers. Claims for physicians' services are submitted and paid using California-specific "X-Codes."

FAC ¶ 37.

The Exhibits attached to the Supplemental Submission clearly show that Plaintiffs have failed to allege that anything in these claims submitted by providers to Medi-Cal was false. Plaintiffs' Supplemental Submission confirms that providers' claims do not contain any information relating to AWP or Direct Price. Indeed, the only drug pricing information contained in a claim is the provider's billed "usual and customary charge" (*see* Pls.' Ex. D at 6 (explaining what the providers are to enter in the "Charge" field)) – an amount that Plaintiffs have never alleged was false or inflated.

If this Court were to allow Plaintiffs to proceed with a False Claims Act case without the existence of a false claim, the False Claims Act would be stretched beyond recognition.

Plaintiffs' Supplemental Submission proves that no such false claim exists here. Accordingly, Plaintiffs' FAC must also be dismissed pursuant to Rule 12(b)(6).

CONCLUSION

For these reasons, as well as those stated in Defendants' briefs in support of their motion to dismiss, the Defendants listed below respectfully request that the Court grant Defendants' motion to dismiss Plaintiffs' FAC in its entirety.

Dated: October 5, 2006

SUBMITTED ON BEHALF OF ALL LISTED DEFENDANTS BY:

/s/ Brian J. Murray

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